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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,422	02/27/2004	Boris Y. Shekunov	FER-14668.001	5255
7609 7590 07/12/2007 RANKIN, HILL, PORTER & CLARK, LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405			EXAMINER DRODGE, JOSEPH W	
			ART UNIT 1723	PAPER NUMBER
			MAIL DATE 07/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,422

Applicant(s)

SHEKUNOV ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

In view of the Appeal Brief filed on 03 May 2007, PROSECUTION IS HEREBY REOPENED. as set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:



David Roy Sample.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Sievers et al patent 5,639,441. For claim 16, Sievers also disclose apparatus features of extraction vessel 20, means for removing formed particles 22,34,24, 1st supercritical fluid reservoir source 10, 1st pump 12, 2nd solution reservoir source 14, 2nd pump 16, and a restrictor, backpressure maintaining means for removing the mixture at column 11, line 66-column 12, line 5. Sievers infers that flow control restrictors are interchangeable, or combinable, with flow control release valves, as instantly claimed, at column 10, lines 55-56. Also, the combination of vessel cap, septum and puncturing pin at the embodiment of column 12, line 49-column 13, line 10 constitute a release valve. Means for removing the formed particles and separating them from entrained fluids are disclosed at column 12, lines 1-10 and column 13, lines 7-12. If necessary, relative solubilities and presence or absence of supercritical state of the fluids contained in the various reservoirs and pumps do not define structural limitations.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sievers et al patent 5,639,441. Sievers et al disclose particles produced by process steps employing use of solvents, solutes and supercritical fluids, forming of a solution and followed by precipitation and separation of particles (see especially column 6, lines 17-36 and column 7, lines 15-20). If necessary, a wide variety of types of particles are disclosed (column 5) and of relatively uniform and fine size ranges (column 5, lines 17-20). Means to vary particle size ranges are disclosed at column 12, lines 41-48.

If necessary, the following also apply: when the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process, it anticipates or makes

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obvious the claimed product. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

When the examiner has found a substantially similar product as in the applied prior art, the burden of proof is shifted to applicant to establish that their product is patentably distinct and not the examiner to show the same process as making. *In re Brown*, 173 USPQ 685 and *In re Fessmann*, 180 USPQ 324.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sievers et al patent 5,639,441, if necessary, in view of, or as evidence by, the now cited publication "Introduction to Supercritical Fluids" and/or the publication "Supercritical Fluid" (by Wikipedia).

Sievers et al disclose producing of particles [as in claims 10 and 15] comprising providing supercritical fluid, 1st solvent soluble in such fluid, 2nd insoluble solvent, the 2nd solvent optionally being partially soluble in the 1st solvent, and solute, contacting these together to form a solution, then contacting the solution with supercritical fluid to extract 1st solvent from the solution and precipitate the solute in the form of particles suspended in the 2nd solvent (all disclosed at column 5, line 66-column 6, line 61, column 6, line 66-column 7, line 5 indicate that the solution of solvents and solute are formed before contacting with supercritical fluid).

The solute contains a biologically active substance as in claims 2 and 11 (column 5, lines 22-36). The supercritical fluid is carbon dioxide as in claim 3 (column 6, line

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44). There may be plural solutes as in claim 4 (column 5, lines 36-40). There is also a 2nd solute comprising a polymer, wax or lip as in claims 5 and 12 (column 5, line 37).

The 1st solvent may be an alcohol or acetone organic solvent as in claims 6, 13 and 7 (column 5, lines 66-67 and column 6, line 51) while the 2nd solvent is water (column 6, lines 57-59) as in claim 8. The particle size is from 10 nm to 10 microns (column 6, lines 33-36) for claims 9 and 14.

Both of the fluids/solvents may be or include different supercritical fluids or liquids (column 6, lines 49-52). This portion of text in combination with text of column 7, lines 15-20 gives the option of one of the supercritical fluids/liquids entering the gaseous phase and such fluid/liquid and/or co-solvent thereof (column 6, lines 53-56) precipitating a gas-borne dispersion or suspension of particles while the other supercritical fluid or liquid remains, at least initially in supercritical state. Such dispersion may, in a preferred embodiment comprise particles of solid or liquid and may comprise the dissolved substance in solution or suspension, optionally in an organic solvent such as methanol (column 6, lines 17-24 supported by column 5, line 66-column 6, line 4 and column 6, lines 49-56).

The claims also require that the particles are precipitated to form a suspension in second solvent and separated from the first solvent dissolved in supercritical fluid, while the supercritical fluid remains in a supercritical state. Sievers apparently discloses such precipitation and formation of particles to occur as pressures are rapidly lowered and one of the fluids (supercritical fluids) enters the gaseous phase to initiate precipitation and formation of particles (column 7, lines 15-20). Sievers does not state that all of the

supercritical fluids enter a gaseous phase. Further, Sievers also teaches that the first fluid may be chosen to comprise water, methanol or ethanol (column 6, lines 49-51), with such water, methanol or ethanol being in a supercritical state (column 6, lines 37-44). Fluids such as methanol and water are also disclosed as "mutually soluble", hence constitute solvents and supercritical fluids, simultaneously. Sievers further discloses that the second fluid may be chosen to comprise another supercritical fluid or liquid with such fluid or liquid, preferably being carbon dioxide or a mixture of carbon dioxide and an additional supercritical fluid/ethanol or fluoroform (column 6, lines 41-53). The carbon dioxide mixture is depicted as having advantages of low chemical reactivity, safety and relatively low cost.

As pressures and temperatures are rapidly lowered, the different supercritical fluids (or supercritical fluid/solvents) change from supercritical to gaseous phase, with induced precipitation at different points of time since the different supercritical fluids/solvents have different critical temperatures and pressures. Therefor, at a certain point, the suspension of particles would have begun to precipitate out, while one or more of the supercritical fluids remains in supercritical state. For instance, the Wikipedia table (pages 2-3) and the Critical processes table (pages 2-3) give critical pressures and temperatures for methanol and water that are substantially higher than carbon dioxide, while fluoroform and ethanol have relatively lower temperatures and pressures.

In summary, it would have been obvious to one of ordinary skill in the art to have practiced the Sievers method by selecting and choosing a plurality of supercritical fluids

and solvents having different critical pressures and temperatures, thus remaining in supercritical state for different periods of time, such as methanol, water, carbon dioxide and ethanol, as evidenced as necessary by the publications, in order to synergistically solubilize the wide range of ingredients and substances present (column 5, lines 22-40, etc. of Sievers), and to take advantage of the relative safety, low chemical reactivity and low costs of such combination.

Applicant's arguments filed on May 3, 2007 in the Appeal Brief have been fully considered but they are not persuasive. It is argued that Sievers does not disclose separation of a first solvent from the suspension of particles while the supercritical fluid is in a supercritical state. The rejection of independent claims 1 and 10 and claims dependent therefrom now extensively discusses which of various fluids constituting both solvents and supercritical fluids that are mutually soluble may be used together and motivation for choosing such combination of fluids. It is submitted that in particular, column 6, lines 17-20 and column 7, lines 15-20 indicate that one supercritical fluid may pass into a gaseous state while the other supercritical fluid remains in a supercritical state. The claims are broad enough to read on processes that allow one of a plurality of supercritical fluids to remain in a supercritical state while other fluids enter a gasous state.

It is speculated that the method of Sievers would result in the formation of a gas-borne dispersion, rather than a suspension in liquid or specifically water. However, Sievers merely states that 'at least one of the fluids enters the gaseous phase and

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precipitates a dispersion of the particles (in remaining fluid). Nowhere is it taught that the particles are dispersed into a gaseous phase, although both the embodiments of column 13, lines 4-10 and column 12, lines 12-14 teaches particles becoming suspended in an aerosol (gas-liquid mixture).

With respect to claim 16, it is argued that Sievers does not disclose a release valve that functions to separate first solvent from particles of solute suspended in a second solvent. Sievers only disclosing single opening to release entire mixture of components to region of lower pressure. It is submitted that such process step of separating is not accompanied by corresponding structure, function of a valve being generally understood as removing substances from a single opening or outlet of a vessel. If needed, Sievers does suggest downstream treatment or separation (column 12, lines 6-8)

JWD

July 6, 2007


JOSEPH DRODGE
PRIMARY EXAMINER

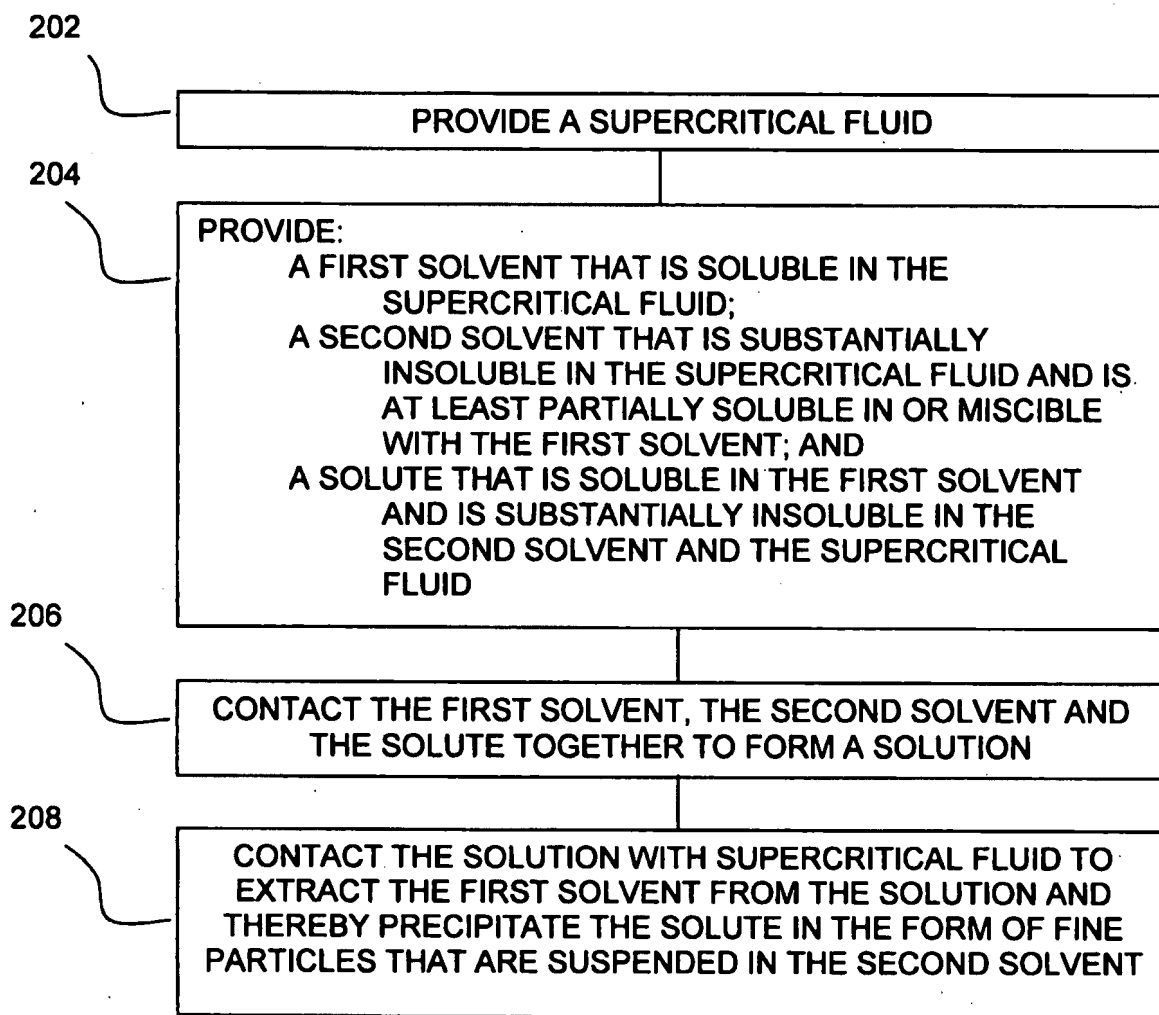


Fig. 1

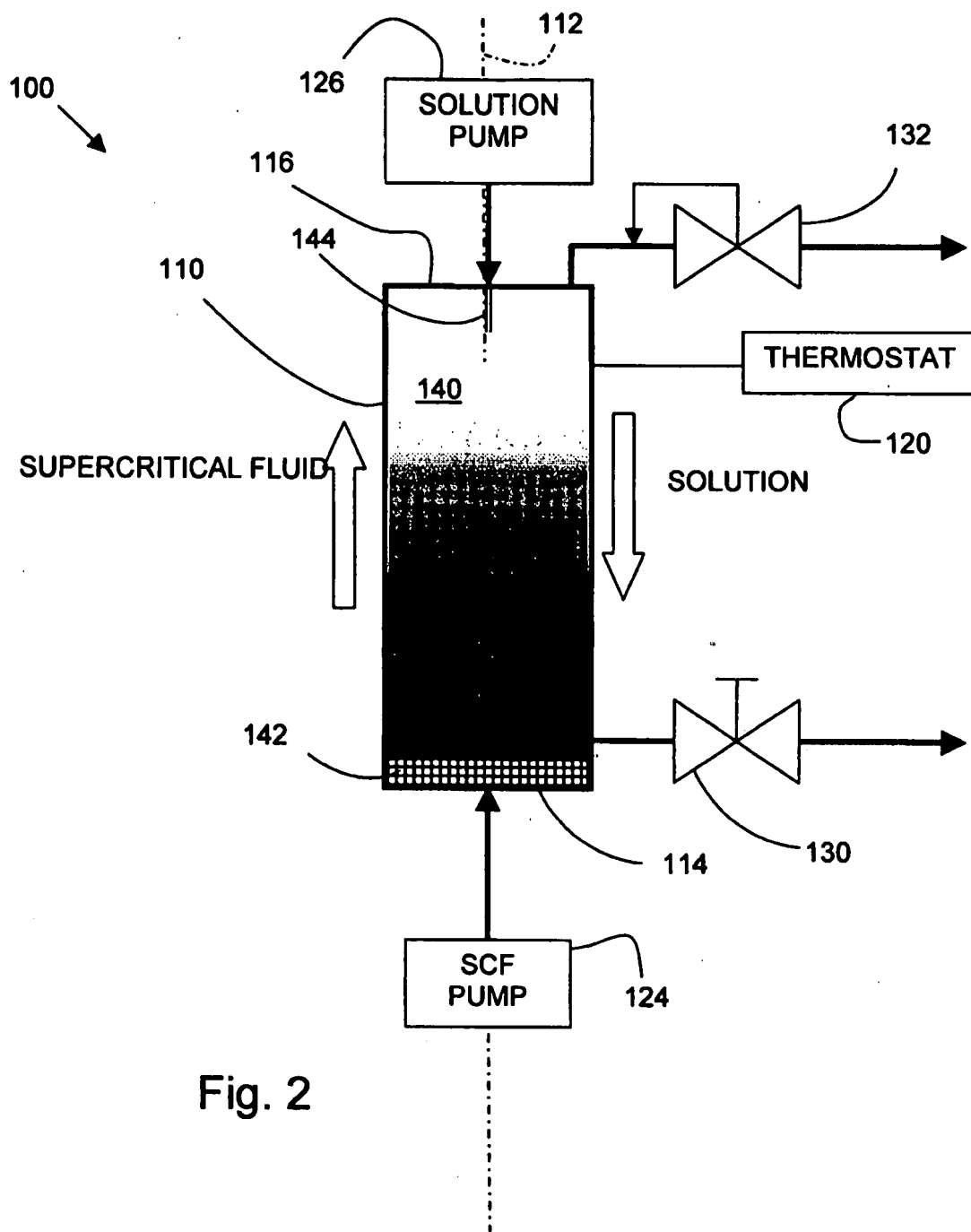


Fig. 2

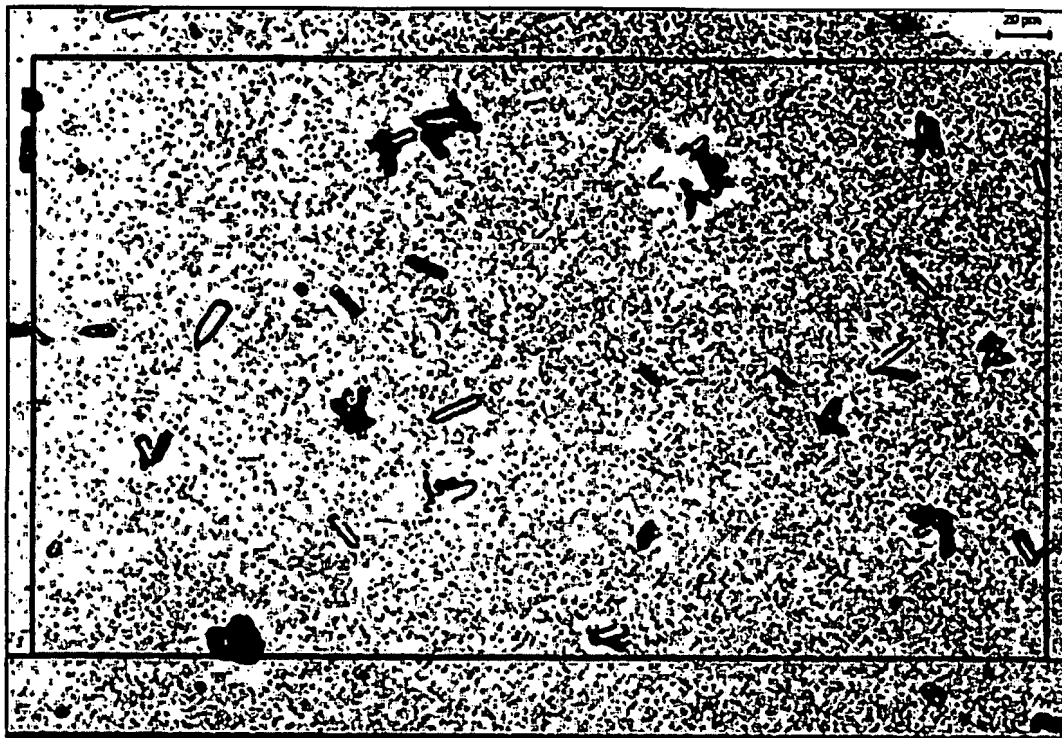


Fig. 3

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